

## PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

REC'D 13 JUL 2004

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(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0351025373	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/AU2004/000490	International filing date (day/month/year) 14 April 2004	Priority date (day/month/year) 15 April 2003	
International Patent Classification (IPC) or national classification and IPC Int. Cl. 7 C07F 9/09, 9/10, 9/12, 9/117, A61K 9/08, 31/661, 31/6615, 31/683, 31/685, A61P 9/00, 23/00, 25/24			
Applicant VITAL HEALTH SCIENCES PTY LTD et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a.  (sent to the applicant and to the International Bureau) a total of sheets, as follows:
    - sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b.  (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report   |
| <input type="checkbox"/> Box No. II           | Priority  |
| <input type="checkbox"/> Box No. III          | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV           | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI           | Certain documents cited   |
| <input type="checkbox"/> Box No. VII          | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII         | Certain observations on the international application   |

Date of submission of the demand 18 June 2004	Date of completion of the report 30 June 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  S.R. IDRUS Telephone No. (02) 6283 2659

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000490

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:
- international search (under Rules 12.3 and 23.1 (b))
  - publication of the international application (under Rule 12.4)
  - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- the international application as originally filed/furnished
- the description:
- |                                      |   |
|--------------------------------------|---|
| <input type="checkbox"/> the claims: | pages                  as originally filed/furnished                        |
|                                      | pages*                received by this Authority on      with the letter of |
|                                      | pages*                received by this Authority on      with the letter of |
- |  |   |
|--|---|
| <input type="checkbox"/> the drawings: | pages                  as originally filed/furnished                            |
|  | pages*                as amended (together with any statement) under Article 19 |
|  | pages*                received by this Authority on      with the letter of     |
|  | pages*                received by this Authority on      with the letter of     |
- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3.  The amendments have resulted in the cancellation of:
- the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to the sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/000490

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1-16	YES
	Claims	NO
Inventive step (IS)	Claims 1-16	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-16	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

The International Search Report identified the following citations:

- D1) AU 43870/00
- D2) Derwent Abstract Accession No. 26921 K/11
- D3) Derwent Abstract Accession No. 1981-89192D/48
- D4) GB 1,121,683
- D5) STN File CA, Abstract 139:399976
- D6) WO 2001/046204
- D7) GB 2 227 662

Citations D1-D5 are the most relevant.

None of the citations teaches or fairly suggests the preparation of phosphorylated derivatives of pravastatin, atorvastatin, venlafaxine or mixtures thereof.

Accordingly, Claims 1-4, 6, 13, 14 and their dependent claims 15-16 are novel and involve inventive step in light of the citations.

Claims 5 and 12 relate to a process for phosphorylating secondary alcohols and the product of that process wherein the process involves reacting the secondary alcohol with  $P_4O_{10}$  in the presence of an alkali salt of a fatty acid. The problem faced by the inventor of the present application is to overcome the disadvantage associated with previous methods used to phosphorylate secondary alcohols, namely that of a significant degree of dehydration of the secondary alcohol to form a double bond (page 4 lines 13-15). And the inventor proffered the solution of the use of an alkali metal salt of a free fatty acid. Suitable alkali metal salts of fatty acids include the sodium and potassium salts of oleic or valeric acid.

None of D1 to D5 discloses the use of an alkali metal salt of a fatty acid.

Accordingly, Claims 5 and 12 and their dependent claims are novel and involve inventive step in the light of D1 to D5.

The phosphate and phosphate complex derivatives of the invention are pharmaceuticals with improved characteristics. Accordingly, the claimed subject matter has industrial applicability.